



CALL FOR RESEARCH PROJECTS

Rules for Submission

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Executive Summary

This document describes the Call for Research Projects in the Share4Rare (S4R) platform. S4R uses collective intelligence for the generation of awareness and advanced knowledge to perform research in the field of rare diseases.

Share4Rare. The platform

The mission of Share4Rare (S4R) is to enhance research in rare diseases by generating knowledge collaboratively. Conceived as a platform for interaction between patients and caregivers, S4R promotes communication between users who share needs, doubts and daily challenges.

On the other hand, S4R offers researchers a secure infrastructure to carry out their research, with the accompaniment of a team of professionals trained to provide personalized support and facilitate the research process.

Benefits that Share4Rare brings to the research team in the implementation of the project

- Advice from a team specialized in data-driven research initiatives in the field of rare diseases.
- Tools to facilitate research projects, including forms, scales, support material, guides and recommendations.
- Support from Share4Rare team for registration, validation and enrollment of study participants (in case the applicant is responsible for the participants' recruitment).
- Collection of data and clinical information provided by patients and caregivers in a secure and confidential environment.
- Access to data analysis services.
- Advice and support in the dissemination of the research results among participants.

Aim of the call

The objective of this Call is to select research projects to be implemented and developed on the Share4Rare platform.

Research topics

Whether qualitative or quantitative research, the projects that Share4Rare encourages are those that facilitate the understanding of aspects of the rare disease such as its impact on the quality of life of people who suffer from it or who live with it, the description of the natural history of the disease, the prognosis of the disease, etc.

Calendar

This Call will be open from **March 15th 2024 to July 15th 2024 at 17:00 CEST**.

Once the call is closed, an evaluation process will take place.

Application process and documentation

Applicants must fill in the **contact and pre-proposal form** with the basic information on the project and the data from the organization and the person responsible of the project. They must also fill in the **application form** providing all the required information about the project.

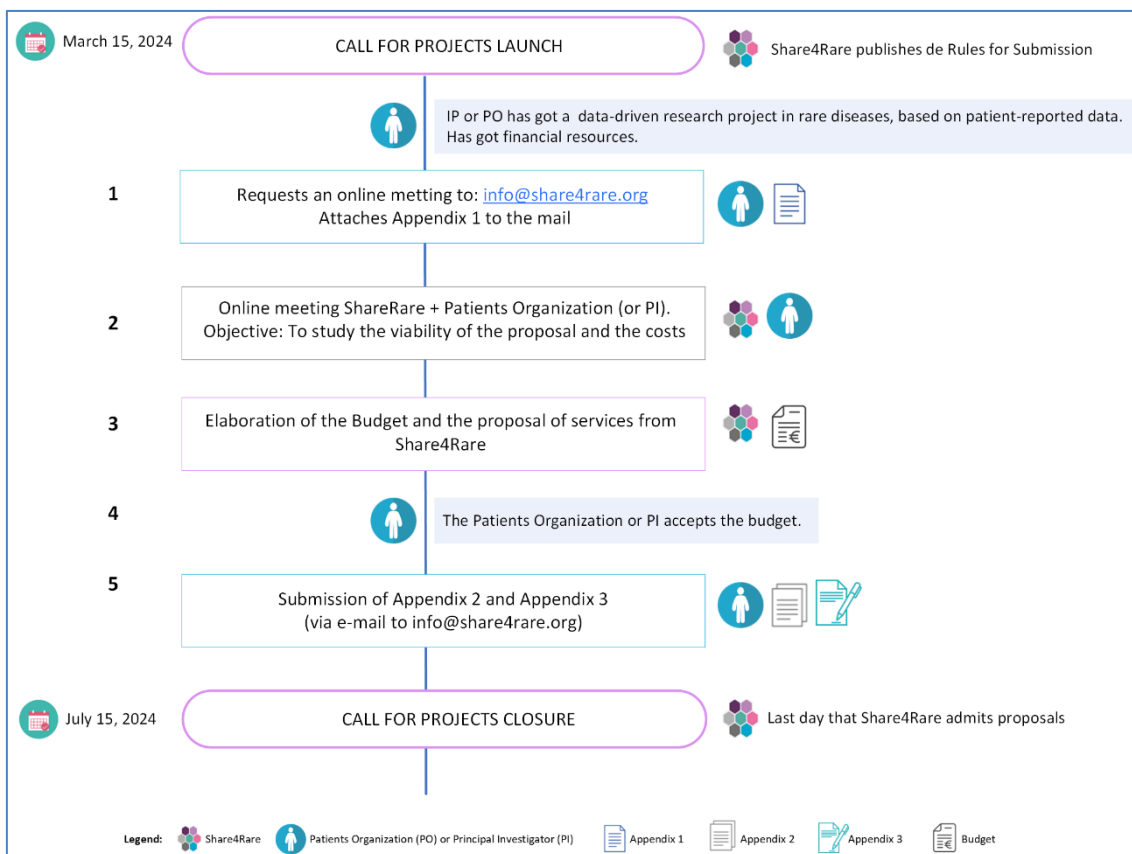
Finally they must sign the **financial commitment** letter, stating that applying organization has the necessary financial resources to carry out the project.

These three documents must be completed and emailed to the attention of the Share4Rare Coordinator: info@share4rare.org within the specified period. The forms and the letter of financial commitment can be found in **Appendices 1, 2 and 3**.

Before sending the documents, applicants shall ask the Share4Rare Coordinator for an advisory meeting with a double objective: assessing the viability of the proposal and the proposal of services needed from Share4Rare.

Based on the information and agreements from this meeting, S4R Coordinator will prepare a Budget and proposal of services. Once approved by the Organization or responsible of the Project, him/she will send the financial commitment letter (Appendix 3) and the Submission form (Appendix 2), which will contain more information and details.

The following figure displays the submission process:



Language of the application

Proposals must be written fully in one of the following languages: Spanish, Catalan or English.

Who can apply?

Patients' organisations or academic institutions and other related stakeholders interested in promoting research in which patients are key for the gathering of relevant information about the rare disease.

Evaluation process

The evaluation process is composed of two stages: (1) Admission and (2) Assessment.

Stage one: Admission

During this stage, the Share4Rare (FSJD) Coordinator will verify the eligibility of the applications, assuring the compliance of all criteria published in these Rules of Submission.

Applications submitted within the established period and written entirely in Spanish, Catalan or English will be accepted. Applications must be accompanied by the contact form and the letter of financial commitment.

Applications that are not eligible will be refused and applicants will be notified.

Stage two: Assessment

Once the admission criteria have been checked, the assessment process will be carried out.

The Share4Rare (FSJD) Coordinator will evaluate each application based on the information shown on the **application form**.

If needed, the Share4Rare (FSJD) Coordinator may request an online interview to the applicant in order to obtain more information or details on the proposal.

The assessment will take into account the following criteria (Scoring 1 to 10):

- a. Quality and innovation of the proposal/research question.
- b. Study or Project responds to a relevant need from the target patients and it involves them for the study's design.
- c. Sample size is adequate to answer the research hypothesis.
- d. Uniqueness of the study (scope of research, participation of researchers/patients at an international level, etc.).
- e. The proposal considers participation in dissemination and communication actions of the project among and outside the Share4Rare community.
- f. The proposal considers the creation of informative and educational content related to the study to nourish the Share4Rare platform.

- g. The applicant is a member of the Share4Rare community or plans to register as a Patient Organization to strengthen the Share4Rare community and to serve as a reference for patients affected with the disease that the entity represents.

The minimum threshold to retain an application for each individual criterion is 7. Proposals that do not meet these minimum criterion will not pass the evaluation process.

Feedback on the evaluation process

The Share4Rare Coordinator will send a decision letter and an evaluation report to all eligible applicants.

The Share4Rare Coordinator will formally reject all applications not eligible or failing to reach any of the threshold scores for evaluation criteria. Rejection does not prevent an applicant to apply again to subsequent calls.

Appeal Procedure

Applicants have 20 calendar days from the date of sending of the formal decision letter to request clarification of the evaluation process. This can be done by submitting a request to Share4Rare coordinator at the email address: info@share4rare.org. Share4Rare coordinator will confirm receipt and respond to the request within a maximum period of 15 calendar days.

Financial contribution

After the initial meeting among the the applicant and the Share4Rare Coordinator, and based on the information yielded by the applicant, the Share4Rare Coordinator will elaborate an estimate budget.

Once the budget is accepted, the applicant agrees to assume the cost of the project and will send the Share4Rare Coordinator the financial commitment letter along with the application form.

The amount of financial contribution will be dedicated to cover:

- Ethics committee application.
- Guidance of patients for their enrolment and during the research project.
- Creation of the landing page for the participants' enrollment to the study.
- Design and implementation of questionnaires for patients' data collection.
- Translation of the questionnaires, scales and landing pages to other languages, if needed.
- Design of engagement and communication activities to promote the research project.
- IT support to develop the research project on the S4R platform
- Project management (includes regular meetings with the applicant/research team).
- Data analysis services.
- Report of the results
- Scientific publication advisory support.

The research project will begin with the approval of the proposal and 30 natural days upon payment of 50 % of the budget. The remaining 50% will be due in two terms: 25% in the mid-term of the project, and 25% at the end of it.

General obligations

The use of Share4Rare should be cited on the same basis all software that was used to generate and analyse data in scientific publications. Share4Rare team members won't appear as author in the publications (unless this is requested).

Confidentiality

The confidentiality of the applications presented is guaranteed throughout the entire process. In any case the general characteristics of the applications may be disseminated and, in course, the name of accepted projects (included logo) a brief description, the name of the project and his/her photo may be published through, without limitation, press releases, e-mails, and website to communicate information about the Call.

The information content and the results of the projects, as well as any other information and documentation exchanged within the framework (including information regarding other project participants) of the Call shall be considered confidential information (hereinafter the "**Confidential Information**").

The Share4Rare Coordinator, applicants and any other person attending the activities, shall undertake, unless prior written authorization is received from the other parties, to:

- Keep the Confidential Information strictly confidential and not to disclose it to any Third Parties.
- Not use the Confidential Information for any purpose other than the development of the project.
- Restrict access to the Confidential Information exclusively to those employees, collaborators, and/or professional advisers that, under the obligation of confidentiality, need to access the Confidential Information strictly for the development of the Project.
- Return the Confidential Information without keeping any copies or summaries when the Call is terminated.

Confidential Information does not include information that: (a) is or becomes publicly known or available before or at the moment at which it is received or obtained; (b) the information is obtained without being subject to any confidentiality obligation; or (c) the disclosure of the information is required by law or judicial order in which case said disclosure request must be previously notified, in advance, to the other party, so that the latter can implement the actions it considers necessary to prevent or limit the disclosure.

Data Protection

The applicants authorize Share4Rare Coordinator to access, use, and share information from the projects submitted to the Call, including all documents referred to therein, whether submitted

at the time of the application or at a later stage, for the purposes of this Call and to the extent necessary, including but not limited to, the evaluation, selection and following up the projects.

Data subjects can ask for more information and/or exercise their rights of access, rectification, removal, restriction, portability, and objection before the Data Protection Officer of FSJD at C/Santa Rosa, 39-57, 08950 Esplugues de Llobregat, Barcelona, or at the e-mail address hospitalbarcelona.dpd@sjd.es.

Other obligations

- Applicants shall collaborate with Share4Rare representatives on the implementation of the activities indicated in the proposal in line with the highest quality standards and state-of-the-art scientific development, and in compliance with the provisions of all legal obligations under applicable EU, international and national law.
- Applicants are sole responsible for the recruitment of users for their research study, which will be supported by Share4Rare dedicated staff on the registration, validation and enrolment to the study.
- Applicants must provide any information requested by Share4Rare in writing at any time to verify the proper implementation of the activities in compliance with the general obligations.
- Applicants must immediately inform Share4Rare of any situation affecting the implementation of the activities foreseen in the proposal. In particular the applicant must promptly provide any relevant information on:
 - any obstacles and/or limitations that may prevent or are likely to affect or delay implementation of the activities foreseen in the proposal;
 - any relevant changes in the applicant legal, financial, technical, organisational or ownership status that may affect implementation of such activities;
 - any circumstance that may affect the applicant's due diligence in the management of the Financial Contribution or the compliance with the obligations of this Call for Research Projects.

Appendix 1 - Contact Form and pre-proposal

Contact details of the person in charge of the proposal
Name and Surname
Email
Legal name of the organisation
Address of the organisation
Disease of interest, focus of research
Title of the project
Objective/s of the project (max. 1000 characters)
Summary of what you intend to do / study (max. 1 page)

Regarding the population of study:

What is the expected sample size?

In what countries is the study going to be held?

In what languages is the study going to be held?

Regarding the timing of study:

How long is the Project going to last? (Please, take into account that the Budget will be annual, but it is convenient to have an estimation of the total duration of the Project, as well as if there will be any iterations on the questionnaires)

Please, complete this contact form and send it via email to info@share4rare.org.

Appendix 2 – Application Form

Research opportunity details
Title of project
Name and affiliation of the person in charge of the proposal
<p>Is a patient organisation involved in the research study? Yes/No.</p> <p>If yes, does this patient organisation have a scientific advisory board? Yes/No.</p>
<p>Research experience of the person in charge of the proposal (or the group) during the past 5 months, if any</p>
<p>Stage of the project: Funded/Pre-funding (Please, take into account the mandatory financial contribution and the payment terms)</p>
<p>Has the project been approved by an ethics committee? Yes/No If yes, please attach the correspondent approval.</p>
<p>Please give a summary of the proposed activity in the format provided below (3 pages max.):</p> <p>Study title:</p> <p>Justification of the need:</p> <p>Hypothesis:</p> <p>Objectives:</p>

Regarding the study:

Target population:

- **Who can participate? (patients, caregivers, specific disease, age rank)**

- **In what countries is the study going to be held?**

- **In what languages is the study going to be held?**

- **What is the expected sample size?**

Methodology:

Write down the name and features of each one of the questionnaires that will be used:

- **Questionnaire 1:** (Name/Title). Validated/Not validated. Number of questions. Type of information collected

- **Questionnaire 2:** (Name/Title). Validated/Not validated. Number of questions. Type of information collected

- **Questionnaire 3:** (Name/Title). Validated/Not validated. Number of questions. Type of information collected

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- **Questionnaire 4:** (Name/Title). Validated/Not validated. Number of questions. Type of information collected

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- **Questionnaire X:** (Name/Title). Validated/Not validated. Number of questions. Type of information collected

Describe the data analyses needed to be done by Share4Rare: what variables and what statistical tests

<p>How will this Project benefit to people affected by <u>(name of disease)</u> _____?</p>
<p>Patients recruitment: Will you need support in recruiting patients? (Yes/No) In case the applicant will recruit the patients, please describe how it is going to be done. Please, take into account that Share4Rare will give technical support and guidance to patients enrollment through the online registration process.</p>
<p>Has the project sponsorship of a pharma company? Yes/No</p>
<p>If yes, which is the purpose of this support?</p>
<p>How will you feedback to Share4Rare and the people who get involved regarding how their involvement has made a difference and of the outcome of the research? (Examples: sending a <i>thank you</i> letter with the final report, through a webinar, a video, an infographic document, etc.)</p>
<p>Do you have any dissemination actions planned that will bring visibility to the study and help recruit participants? Please describe them briefly.</p>
<p>Is the applicant (Patient Organization) a member of the Share4Rare Community or is planning to be?</p>

Please, complete this application form and send it to info@share4rare.org.

Appendix 3 – Letter of Financial Commitment

From:

(Name and surname of the proposal's responsible)

(Name of the Organization or Institution)

(Mailing Address)

(E-mail)

To:

Begonya Nafria Escalera

Share4Rare Coordinator

Fundació Sant Joan de Déu (FSJD)

C/ Santa Rosa, 39-57, 08950 Esplugues de Llobregat, Barcelona

info@share4rare.org

Dear,

I declare that I am aware of the economic conditions required for the development of the research project on the Share4Rare platform and that I will comply with the following financing agreements:

- The annual cost of the project will be financed by the applicant.
- The applicant commits to make a first payment of 50% of the budgeted cost 30 days after the start of the project, 25% of the budget cost in the middle of the project, and the remaining 25% at the end of the project.

Likewise, I undertake to comply with the financial obligations described in the Rules for Submission and to inform of any change or financial situation that may affect the development of the project.

Sincerely,

(Applicant's signature)

(Applicant's name and surname)

(Place and date of the signature)

Please, fill in this letter of financial commitment and send to info@share4rare.org.